

## REMARKS

The Listing of Claims is presented as a matter of convenience. No amendments are presented in the Listing of Claims. No new matter is entered.

Claims 1-57 are pending. Claims 1-25 and 45-53 were previously withdrawn according to the Restriction Requirement mailed October 2, 2008. Claims 26-44 and 54-57 stand rejected.

Reconsideration is respectfully requested in light of the following remarks.

### **Claim Rejections – 35 USC § 102(e)**

Claims 26-38, 40, 42-44 and 54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0194201 (“Wilbanks et al.”). In the Office Action dated July 1, 2011, the Examiner asserts that “the effective filing date under 102(e) of Wilbanks et al. is 5 June 2001” which is the earliest provisional application date filed as US 60/296,018. (See Office Action, page 10, par. 3).

Applicants respectfully disagree on the basis that the subject matter relied upon by the Office Action is not entitled to the filing date of 5 June 2001 of the Wilbanks provisional application. In applying the teachings of Wilbanks et al., the Examiner quotes exclusively from US Patent Publication 2002/0194201 (Wilbanks et al.; Office Action dated July 1, 2011, pages 4-6). The provisional Application US 60/296,018, which the Examiner relies on to determine the effective filing date under 102(e) of Wilbanks et al., fails to disclose the teachings of Wilbanks et al. that the Examiner uses in claim rejections under 102(e). For example, on pg. 4 last paragraph of the Office Action dated July 1, 2011, the Examiner alleges that “Wilbanks et al. teach a query of results stored as at least one new relationship in the entity-relationship model and the establishment of a confidence level that is assigned to at least one of the relationships (paragraph 0013)”. However, the provisional application US 60/296,018 is silent on any teaching about the establishment of confidence levels. Thus, the filing date of the provisional Application US 60/296,018 is not available for the determination of the effective filing date under 102(e) of Wilbanks et al.

Thus, the effective filing date under 102(e) of Wilbanks et al. is May 13, 2002, which is the actual filing date of the application published as US 2002/0194201. Moreover, the invention as claimed in the instant Application was conceived and reduced to practice prior to May 13, 2002, as discussed below and as evidenced in the Declaration Under Rule 131 submitted previously. Therefore, Wilbanks et al. is not available as prior art under 102(e). Thus, the Applicant respectfully requests the claim rejections under 35 U.S.C. 102(e) to be withdrawn.

### **Declaration Under 37 CFR 1.131**

In the Office Action dated July 1, 2011, the Examiner states that “[t]he Declarations filed on 7 March 2011 under 37 CFR 1.131 have been considered but are ineffective to overcome the prior art reference” (see Office Action, pg. 10, par. 1). Firstly, the Examiner alleges that “[t]he effective filing date under 102(e) of Wilbanks et al. is 5 June 2001.” As discussed above, the Wilbanks et al. provisional application is silent with respect to the subject matter relied upon by the Office Action, thus the effective date under 102(e) of Wilbanks et al. is May 13, 2002.

Further, on page 10, paragraph 4 of the Office Action dated July 1, 2011, the Examiner asserts that “the actual dates of acts relied upon to establish diligence must be provided in the Declaration (see MPEP 715.07(a))”. The following is a quotation of the appropriate paragraph of MPEP 715.07(a):

Where conception occurs prior to the date of the reference, *but reduction to practice is afterward*, it is not enough merely to allege that applicant or patent owner had been diligent. Ex parte Hunter, 1889 C.D. 218, 49 O.G. 733 (Comm'r Pat. 1889). Rather, applicant must show evidence of facts establishing diligence. (emphasis added)

Here, the conception **and** the reduction to practice of the invention occurred before May 13, 2002, the effective date of the Wilbanks et al. reference under 102(e). Thus, the Applicant asserts that neither the facts establishing diligence, nor the actual dates of acts relied upon to establish diligence need to be provided.

In addition, on page 10, paragraph 5 of the Office Action dated July 1, 2011, the Examiner found the Declarations filed on March 7, 2011 “insufficient to overcome the Wilbanks et al. reference because the exhibits relied upon (herein listed as Exhibits 1-4) are not specifically referred to in the Declarations in terms of what they are relied upon to show”. Applicants respectfully disagree on the basis that Exhibits 1-4 are self-evident in what they show, in particular with respect to the individual claim elements of the instant Application, as follows.

Regarding “a computer comprising a structured database to store and access genomics information, wherein the computer permits the computation of complex relationships among genes and/or gene products found within the genomics information”, reproduced from the pending claim 26 of the instant application, Exhibit 1 lays out multiple examples for “complex relationships among genes and/or gene products” on pages 1-7 and on page 7, states “...but as our computational sophistication grows”, indicating the use of computerized methods. Further, on page 16 of Exhibit 4, the results of the

computation of complex relationships among genes and/or gene products found within the genomics information are displayed on a computer screen. Page 14 of Exhibit 4 discusses results with respect to the coverage by an ontology. On the same page, Exhibit 4 mentions the use of Biocarta canonical pathways – a computer based database known in the art, mapping molecular relationships between proteins, genes etc.- to run the analysis. Lastly, page 6 of Exhibit 4 describes the EAFX analysis as “computationally identify[ing] groups of genes from step 2 that appear to be functionally connected”.

Page 7 of Exhibit 4 displays in simplified form the use of “a structured database to store and access genomics information” displayed as the ontology. “A collection of profiles” are built “using genomics information stored in the database”, i.e. the “ontology”. “User-supplied genomics data” in the form of “micro-array expression data” is input. A scoring function, “Scoring Fn”, outputs a list of “Ranked Profiles” along with a number expressing statistical significance. The numbers are further labeled on page 16 of Exhibit 4 as “PROB” (probability).

In regard to “(a) define a profile model based on one or more profile definition criterion“, page 9 of Exhibit 1 defines some of the EAFX project components under “defin[ing] pathways in a way that is customer-validated”; “identify[ying] connections between expression results and these pathways”; and being “able to identify those connections that do not appear to be the product of random chance” (also see in pending claim 26 “(c) identify one or more profiles that overlap at least a portion of a user-supplied genomics data and determine, for each such overlapped profile, whether the overlap is statistically significant”).

Further, in regard to defining “a profile model based on one or more profile definition criterion”, pages 1-2 of Exhibit 1 provide several examples for definitions of profiles, e.g. based on cell death, wound-healing, and glucose metabolism.

In regard to “(b) build a collection of profiles according to the profile model using genomics information stored in the database”, Exhibit 2, on page 1 reiterates the EAFX project in the first row of the table in a basic difficulty level under the solution column: To form “[s]imple relationships between genes” “Take a set of genes -> Identify all direct facts linking genes. Identify largest connected groupings. Identify links with lots of facts.” On page 16 of Exhibit 4, a number of profiles are ranked in the results of the EAFX analysis on array BR-MDS-MB-435\_cell\_array, under the “PROFILE\_LABEL” column. Page 20 of Exhibit 4, further refers to the “Ingenuity profiles” and page 22 of Exhibit 4 states: “Built & evaluated several Profile types”.

In regard to “(c) identify one or more profiles that overlap at least a portion of a user-supplied genomics data and determine, for each such overlapped profile, whether the overlap is statistically significant”, page 8 of Exhibit 1 defines the question: “what are the chances that the observed overlap between members of set e (expression data) and p (pathway) is due to random chance?” Page 1 of Exhibit 3 reproduces a message by Dan Richards, where he reports: “I worked out the probability (not p-value) calculation for the null hypothesis match.” Dan further provides the computer code in PERL following the note, wherein the comments state: “Compute probability of getting BCP match by chance for null hypothesis of BCP generated randomly.” Page 8 of Exhibit 4 identifies BCP as “Pathway or Biologically Coordinated Program”. Further, Page 11 of Exhibit 4 shows as complete “showing that scores from analyzing actual experiments are better than scores from random experiments”, thus “identify[ies] one or more profiles that overlap at least a portion of a user-supplied genomics data and determine, for each such overlapped profile, whether the overlap is statistically significant”. Page 20 of Exhibit 4 further displays a test demonstrating the non-random nature of the results.

With regard to “(d) analyze one or more statistically significant profiles together with the user supplied genomics data including inspection of database-asserted biological interactions embodied in the one or more statistically significant profiles”, page 15 of Exhibit 4, summarizes the results of the EAFX run. Accordingly, “user-supplied genomics data”, e.g. “Fibroblast data” or “NCI Cancer data” are analyzed and “database-asserted biological interactions embodied in the one or more statistically significant profiles” are “inspect[ed]”. It is concluded that the “[r]esults make biological sense”. Further, page 17 of Exhibit 4 displays the analysis of “select examples” of the “MITF Profile Members” – all statistically significant according to the probability ranking displayed on page 16 of Exhibit 4 – which results in the “ontological assertions listed on the right column, e.g. “growth of tumors”, “expression in tumors”, “curvival of tumor cells”, etc.

Thus, Exhibits 1-4 provide a complete self-contained demonstration that the invention as claimed in the instant Application was conceived and reduced to practice prior to May 13, 2002, the effective date of the Wilbanks et al. reference under 102(e), which is cited in the Office Action dated July 1, 2011. As such, neither the facts establishing diligence, nor the actual dates of acts relied upon to establish diligence need to be provided.

#### **Claim Rejections – 35 USC § 103(a)**

Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0194201 (“Wilbanks et al.”), as applied to claims 26 and 40, and further view of Karp et al. (TIBTECH (1999) Vol. 17, pages 275-281; IDS reference).

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0194201 ("Wilbanks et al."), as applied to claim 26, and further view of Qu et al. (Intelligent Systems in Biology (2002) March/April, pages 21-27; IDS reference; previously cited).

All of the claim rejections under 35 U.S.C. 103(a) rely on Wilbanks et al. as the primary reference. As discussed above, the subject matter relied upon in the rejection is not present in the US 60/296,018 Wilbanks et al. priority document. Thus, the effective filing date of Wilbanks et al. is after the conception and reduction to practice of the instant claims as evidenced in the Declaration Under Rule 131 submitted previously. As Wilbanks et al. is not available as prior art, and neither Karp nor Qu on their own render the instant claims unpatentable, Applicants respectfully request that the claim rejections under U.S.C. 35 103(a) be withdrawn.

The Applicant believes that the pending claims are in allowable condition and respectfully requests that the rejections be withdrawn.

#### CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 27763-705.831) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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